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## (54) Annuloplasty ring prosthesis.

(57) An annuloplasty ring prosthesis has a flexible, annular body including one or more defined lengths (16,30), which are more rigid than the remainder of the body. The flexible body increases in flexibility about its circumference in a direction away from the, or each rigid, defined length and is formed from a plurality of individual wire elements. The elements may be wire strands (14,24) secured in a bundle, positioned in respective lumens (26) of a multiple lumen enclosure (28), or may be layers (38) of one or more wire bands wrapped on one another.

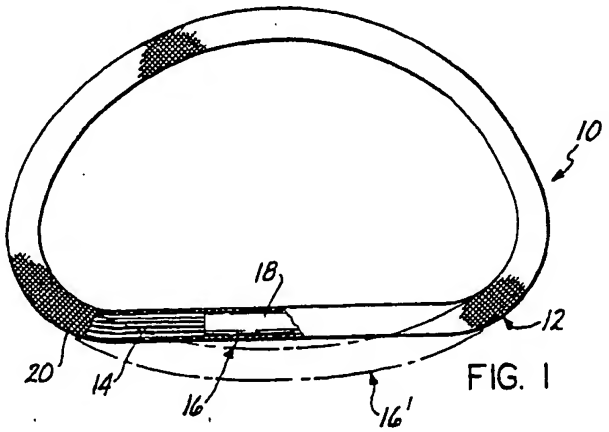


FIG. 1

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## BACKGROUND OF THE INVENTION

The present invention relates to a support for a natural human heart which may be used for the surgical correction of a deformed heart valve, specifically a heart valve which has become dilated. In particular, the present invention relates to an annuloplasty ring prosthesis for implantation about heart valves.

The human heart generally includes four valves. Of these valves the more critical ones are known as the mitral valve, which is located in the left atrioventricular opening, and the tricuspid valve, which is located in the right atrioventricular opening. Both of these valves are intended to prevent regurgitation of blood from the ventricle into the atrium when the ventricle contracts. In preventing blood regurgitation both valves must be able to withstand considerable back pressure as the ventricle contracts. The valve cusps are anchored to the muscular wall of the heart by delicate but strong fibrous cords in order to support the cusps during ventricular contraction. Furthermore, the geometry of the heart valves ensure that the cusps over lay each other to assist in controlling the regurgitation of the blood during ventricular contraction.

Diseases and certain natural defects to heart valves can impair the functioning of the cusps in preventing regurgitation. For example, certain diseases cause the dilation of the heart valve annulus. Dilation may also cause deformation of the valve geometry or shape displacing one or more of the valve cusps from the center of the valve. Other diseases or natural heart valve defects result in deformation of the valve annulus with little or no dilation. Dilation and/or deformation result in the displacement of the cusps away from the center of the valve. This results in an ineffective closure of the valve during ventricular contraction, which results in the regurgitation or leakage of blood during ventricle contraction. For example, diseases such as rheumatic fever or bacterial inflammations of the heart tissue can cause distortion or dilation of the valvular annulus. Other diseases or malformations result in the distortion of the cusps, which will also lead to ineffective closure of the valve.

One method of repairing an impaired valve is to completely replace the valve. This method is particularly suitable for replacing a heart valve when one of the cusps has been severely damaged or deformed. However, presently available artificial heart valves are not as durable as natural heart valves, and it is usually more preferable if the patient's heart valve can be left intact.

While it is difficult to retain a heart having diseased or deformed cusps, the ability to surgically correct the deformation of the valve annulus at least provides the possibility of retaining the patient's valve intact. That is, while the replacement of the entire valve eliminates the immediate problem associated with a dilated valve annulus, presently available heart valves do not possess the same durability as natural heart valves. It is thus desirable to save the valve instead of performing a complete replacement.

Techniques have been developed to repair the shape of the dilated or elongated valve. These techniques, known as annuloplasty, is a surgical procedure of restricting the dilation of the valve annulus. Typically, a prosthesis is sutured about the base of the valve leaflets to restrict the dilation of the valve annulus.

The prosthesis restricts the movement of the valve annulus during the opening and closing of the valve. The general desire in designing a prosthesis is to provide sufficient rigidity to ensure an adequate support of the valve annulus to allow for the possible healing of the valve annulus, while allowing for as close as possible the natural movement of the valve annulus during the opening and closing of the valve. This is particularly important since such prostheses are not normally removed from the heart valve, even if the valve annulus heals to a normal geometry.

Over the years different types of prostheses have been developed for use in annuloplasty surgery. In general prostheses are annular or partially annular shaped members which fit about the base of the valve annulus against the leaflets. Initially the prostheses were designed as rigid frame members, to correct the dilation and reshape the valve annulus to the natural state. These annular prostheses were formed from a metallic or other rigid material, which flexes little, if at all, during the normal opening and closing of the valve. Examples of rigid annuloplasty ring prostheses are disclosed in U.S. Patent Numbers 3,656,185, issued to Carpentier on April 18, 1972; and 4,164,046, issued to Cooley on August 14, 1979. Certain artificial heart valves have also been developed with rigid frame members similar to the rigidity of the described valve prosthesis. An example of this type of heart valve are disclosed in U.S. Patent Numbers 4,204,283, issued to Bellhouse et al on May 27, 1980; and 4,306,319, issued to Kaster on December 22, 1981.

As stated, rigid annuloplasty ring prostheses adequately promote the healing of the valve annulus by restricting valve dilation and reshaping the valve annulus. However, this rigidity prevents the normal flexibility of the valve annulus. That is, a normal heart valve annulus continuously flexes during the cardiac cycle, and a rigid ring prosthesis interferes with this movement. Since it is standard to retain the prosthesis, even after the valve annulus has healed, the rigidity of the prothesis will

permanently impair the functioning of the valve and the associated ventricle. Another disadvantage with a rigid ring prosthesis is the tendency for the sutures to become torn loose during the normal movement of the valve annulus.

Other workers have suggested the use of completely flexible annuloplasty ring prostheses, in order to overcome the disadvantages of rigid ring prostheses. This type of prosthesis is formed with a cloth or other very flexible material frame member. The resulting prosthesis provides little, if any resistance to the dilation of the annulus during the opening and closing of the valve. Furthermore, while these types of annuloplasty ring prothesis offer increased flexibility, such prosthesis fail to correct that valve disfunction due to the deformation of the valve annulus.

A further disadvantage with completely flexible ring prostheses is that the circumference of the ring is not fixed. That is, as the prothesis is being sutured to the annulus using, what are known as mattress sutures, the body of the prosthesis may become bunched at localized areas. This bunching of the prosthesis is generally referred to as multiple plications of the ring prosthesis. The resulting sutured prosthesis will not provide the desired reshaping of the valve annulus.

Examples of completely flexible ring prostheses are disclosed in U.S. Patent Number 4,290,151, issued to Massana on September 22, 1981, and are discussed in the articles of Carlos D. Duran and Jose Luis M. Ubago, "Clinical and Hemodymanic Performance of a Totally Flexible Prosthetic Ring for Atrioventricular Valve Reconstruction", 5 Annals of Thoracic Surgery, (No. 5), 458-463, (November 1976) and M. Puig Massana et al, "Conservative Surgery of the Mitral Valve Annuloplasty on a New Adjustable Ring", Cardiovascular Surgery 1980, 30-37, (1981).

Still further types of annuloplasty ring prostheses are designed to allow for adjustment of the ring circumference, either during the surgical implantation, or as the ring prosthesis during the opening and closing of the valve. This type of adjustable prosthesis is typically designed in combination with a rigid, or at least partially rigid frame member. For example, the ring prosthesis taught in U.S. Patent Number 4,489,446, issued to Reed on December 25, 1984, allows for self adjustment of the prosthesis annulus by constructing the valve frame member in two reciprocating pieces. However, while the resulting prosthesis is adjustable in at least one direction, the individual frame members are formed from a rigid material and thus the prosthesis suffers the same disadvantages with the rigid ring prosthesis discussed above.

Other examples of adjustable ring prostheses are taught in U.S. Patent Numbers 4,602,911, issued to Ahmadi et al and 4,042,979, issued to Angell on August 23, 1977, provide for mechanism of adjusting the ring circumference. In Ahmadi et al the ring prosthesis frame is a coiled spring ribbon which is adjusted by a mechanical screw assembly. In Angell, a drawstring is used to adjust the circumference of a rigid frame member. Again, these ring prostheses suffer from the disadvantages of the rigid ring prosthesis discussed above. The Angell prosthesis could also possess a substantially flexible portion after suturing which could include multiple plications for the reasons discussed above for the completely flexible prosthesis.

A further disadvantage with the Angell prosthesis relates to the design of the adjusting mechanism. The Angell prosthesis includes a rigid partial annular member. The open end of this member forms a gap which can be narrowed by tightening the drawstring. The tighter the drawstring is pulled the narrower the gap. The stress applied to the ring prosthesis during the opening and closing of the valve is primarily directed to the drawstring. Thus failure of the drawstring allows the prosthesis annulus to expand, allowing the valve to dilate.

It would thus be advantageous to design an annuloplasty ring prosthesis having selective flexibility more closely resembling the naturally flexibility of the valve annulus to allow for a more natural movement of the valve during the cardiac cycle, while possessing selected areas of rigidity to allow for the reshaping of the valve. This annuloplasty ring prosthesis should also be formed from a substantially stiff body element to minimize the potential of forming multiple plications about the circumference of the prosthesis during the suturing procedure.

An annuloplasty ring prosthesis which partially achieved these results was taught in U.S. Patent Number 4,055,861, issued to Carpentier on November 1, 1977. The support taught and disclosed is described as being deformable, to an equal degree and simultaneously in all directions within and outside its resting plane, so as to form a skew curve. The preferred support is described as having the elasticity of an annular bundle of 2 to 8 turns of a cylindrical bristle of poly(ethylene terephthalate). In describing the support the individual bristles may either be interwoven, or merely arranged in a side by side relationship.

The extremities of the individual bristles are joined together to prevent the ends from sticking out through the outer cloth sheath by welding, gluing or ligature. It is thus apparent that the overall ring prosthesis will have a single flexibility. This flexibility will be dependent upon the flexibility of the individual bristles, and/or the number of these individual bristles used to construct the support.

While the device taught and disclosed in Carpentier '861 attempts to achieve flexibility in all planes, the resulting device may have a frame member either rigid or equivalent to the discussed completely flexible ring prosthesis, in either case such a ring prosthesis would have the disadvantages associated with such types of ring prostheses.

Furthermore, a ring prosthesis designed in accordance with Carpentier would suffer disadvantages from the excessive wear of the bristles rubbing against each other. This wear would cause flexural fatigue of the structure during normal activity of the valve. The ring prosthesis could also suffer from fatigue due to the differential application of the stress forces applied to the separate bristles or bristle windings. That is, during the natural movement of the valve the normal stress applied to the ring prosthesis would not be equally applied to each of the bristle strands or windings. This could result in fatigue of some of the bristle strands or windings severely affecting the functioning of the ring prosthesis.

EP-A-257874 discloses an annuloplasty ring prosthesis having the features of the precharacterising part of Claim 1. The distinguishing features of the invention are set out in the characterising part of Claim 1

## DESCRIPTION OF THE DRAWINGS

The present invention may be better understood and the advantages will become apparent to those skilled in the art by reference to the accompanying drawings, wherein like reference numerals refer to like elements in the several figures, and wherein:

Figure 1 is a top view of a partially cut-away annuloplasty ring prosthesis of an embodiment of the invention;

Figure 2 is a partially cut-away side view of the ring prosthesis of Figure 1;

Figure 3 is an end view of the prosthesis of Figure 1;

Figure 4 is a partially cut-away top view of another embodiment of the invention;

Figure 5 is a partially sectioned side view of the ring prosthesis of Figure 4;

Figure 6 is a sectional view of the ring prosthesis of Figure 4 taken along line 6-6;

Figure 7 is a sectional view of the ring prosthesis of Figure 4 taken along line 7-7;

Figure 8 is a partially cut-away top view of a further embodiment of the invention;

Figure 9 is a partially sectioned side view of the ring prosthesis of Figure 8;

Figure 10 is a cross-sectional view of the prosthesis of Figure 8 along lines 10-10; and

Figure 11 is a cross-sectional view of the prosthesis of Figure 8 along lines 11-11.

The preferred annuloplasty ring prosthesis includes a substantially annular shaped body element with at least a first defined length about its circumference which is substantially more rigid than the remainder of the elements circumference, with the remainder of the body element gradually increasing in flexibility in a direction away from this rigid length. This body element is formed from a non-corrosive, anti-magnetic material, and is wrapped in a material through which sutures can be drawn to suture the prosthesis to the heart valve annulus.

Preferably the annuloplasty ring prosthesis of the invention is dimensioned to be longer in a longitudinal direction than in a lateral direction, with the overall flexibility of the ring being greater in the lateral direction. In another preferred embodiment, the annuloplasty ring prosthesis is formed in the horizontal orientation, with a substantially straight length along one of the longitudinal oriented sides. The substantially more rigid length lies along this straight portion of the ring prosthesis.

In a still further preferred embodiment, the selective flexibility of the ring prosthesis is orientated to provide that a ratio of the stiffness of the ring in the longitudinal direction over the stiffness in the lateral direction is from about 1.15 to about 2.77. The stiffness is calculated by measuring the spring rates of the ring in both directions.

In one embodiment of the invention, the body element of the ring prosthesis is formed from individual wire strands bundled together. The discrete rigid portion may be formed by crimping together a length of the wire bundle. In another embodiment, the body element is formed from a multi-lumen tubular enclosure and individual non-corrosive, anti-magnetic wire strands positioned individually in each of said tubular enclosure lumens.

In a still further embodiment the body element is formed as a multi-layered structure of one or more individual substantially flat bands of a non-corrosive, anti-magnetic material. The discrete rigid portion of this embodiment can be formed by crimping or spot welding a length of the layers together. This embodiment may be further modified by positioning plastic or other type of elastomer material between the bands, to prevent wear.

The ring prosthesis of the invention is thus formed with a selective flexibility about its circumference while providing a defined structure. That is, the circumference of the prosthesis is defined by the selectively flexible body element which gradually increases in flexibility away from at least one length which is substantially more rigid than the remainder of the body element. The body element

allows the surgeon to correct the dilation and reshape the valve, without sacrificing the desired flexibility needed to allow the valve to more naturally open and close. The selectively flexible body element also ensures that the prosthesis will retain its shape as it is being sutured to the valve annulus to reduce the potential of forming multiple plications.

The annuloplasty ring prostheses described are for suturing to the annulus of a dilated and/or deformed heart valve. The dilation and/or deformation of heart valves may be the result of a disease, natural defect or physical damage to the valve annulus. This dilated and/or deformed heart valve will not completely close, allowing for regurgitation of blood with a closed valve.

The annuloplasty ring prosthesis is surgically sutured to the valve annulus. This prosthesis restricts the circumference of the dilated valve to a more natural dimension, and also provides sufficient rigidity to reshape the valve. The prosthesis of the invention thus restrains dilation of the valve and allows the surgeon to reshape the valve. By properly suturing the rigid and flexible portions of the prosthesis about the valve annulus, the valve functions in a more normal manner than possible with present available annuloplasty ring prosthesis.

Referring now to Figures 1 and 2, an annuloplasty ring prosthesis, in accordance with the invention, is seen generally at 10. Ring prosthesis 10 is formed from a selectively flexible body element, which will be described in greater detail below as being formed from a bundle of a plurality of individual wire strands 14. This body element has a generally oblong or oval shape. The precise dimensions of ring prosthesis 10, as defined by the body element, is dependent upon whether the ring prosthesis is to be implanted about a tricuspid or mitral valve. In any event, the dimensions of ring prosthesis 10 may be designed for any type of valve annulus. Normally, various sized and dimensioned ring prosthesis will be available.

The wire strands 14 are manipulated to provide the prosthesis with any desired shape. The respective ends, not shown, of each of the wire strands 14 are placed in a generally abutting relationship. The wire ends are then held in position by any suitable manner, e.g. crimping.

The illustrated ring prosthesis 10 is designed for suturing about a mitral heart valve. Prosthesis 10 has the shape generally resembling the letter "D". That is, the illustrated ring prosthesis 10 is designed with a generally oblong shape, with one of the longitudinally oriented sides, seen as side 12, being substantially straight. For the purpose of this discussion the description of the substantially straight side 12 shall mean being substantially straight as seen in a direction illustrated in Figure 1. Generally, this substantially straight side 12 comprises from about 1/5 to about 1/3 of the total circumference of the ring prosthesis 10.

The body element of the ring prosthesis 10 is designed with at least one defined length or portion about its circumference which is substantially more rigid or stiff than the remainder of the ring prosthesis, this rigid length being generally indicated at 16. The flexibility of the ring gradually increases in a direction away from this rigid length 16 to provide the overall prosthesis with a selective flexibility. Generally the rigid length comprises from about 1/8 to 1/2 of the ring prosthesis circumference. When suturing the ring prosthesis to the valve annulus, this rigid length is positioned adjacent to the anterior cusp of the mitral valve, or the median cusp of the tricuspid valve.

Preferably, the rigid length 16 is defined along the substantially straight side 12. Generally, the rigid length 16 comprises from about 5/8 to about 3/2 of the straight side 12. Thus this straight side 12 will be sutured adjacent to the anterior cusp of a mitral heart valve, or the median cusp of the tricuspid heart valve.

As seen, a malleable tube 18 is fixed about the bundle of wire strands 14 at a location around these abutting ends. This malleable tube 18 is pinched or crimped down upon the bundle of wire strands 14. The malleable tube 18 functions not only to hold the ends of the wire strands 14 in place, but in this embodiment also defines the rigid length 16 of the ring prosthesis 10. The rigid length 16 may comprise less or more than the entire length of the malleable tube 18. If the rigid length 16 comprises more than the length of the tube 18, then the wire strands 14 are pinched, crimped or welded together for this greater length.

It should be noted that the use of the malleable tube 18 simplifies the forming of the rigid length 16. The abutting ends of the wire strands 14 may be fixed together by an adhesive or by welding, with the rigid length 16 formed by selectively welding or in some other manner fixing the individual wire strands 14 together.

Both the wire strands 14, and the malleable tube 18 are formed from a biocompatible material. This material should also be anti-magnetic. One particular suitable material is a cobalt-nickel alloy manufactured under the trademark ELGILOY by the Egiloy Company, a division of American Gage & Machine Company, 1565 Fleetwood, Elgin, Illinois. This material is also described in US Patent Number 2, 524,661.

Generally, ring prosthesis 10 will vary in size from 24 millimeters (mm) to 38 mm. The number of wire strands 14 used to construct the ring prosthesis 10 is dependent upon the desired flexibility, which is dependent upon the diameter of the wire

strands 14, and the material from which the strands 14 are made. Generally, the individual wire strands 14 will have an outer diameter of from about 0.2mm (0.008 inch) to about 0.6mm (0.022 inch). The number of wire strands 14 used to construct the ring prosthesis 10 will vary from about one to about twelve.

As stated the ring prosthesis possesses a selective flexibility about its circumference. This selective flexibility is dependent upon many variables, e.g. the composition, outer diameter and size of the individual wire strands 14, and the size of the rigid length 16. Generally, by altering these variables the flexibility of the ring prosthesis is selected to position rigid lengths at locations which provide the needed support to the valve annulus and allow the surgeon to reshape a deformed valve.

These variables may be manipulated to provide that the ring prosthesis will be stiffer in the longitudinal direction. The longitudinal direction for the ring prosthesis is the longest length. The prosthesis 10 also includes a lateral direction, which is generally the width of the ring prosthesis 10. The ring prosthesis 10 is designed to provide a ratio of the stiffness of the prosthesis 10 in the longitudinal direction over the stiffness in the lateral direction from about 1.15 to about 2.77.

The stiffness of the ring prosthesis 10 in the longitudinal and lateral directions may be calculated by determining the spring rate of the ring prosthesis 10 for these directions. The spring rate may be calculated by the concept known as Finite Element Analysis. The Finite Element Analysis allows for calculating the spring rate in the longitudinal and lateral directions using the diameter and length of the individual and bundle of wire strands 14, and the rigid length 16. The type of material from which the wire strands 14 and the malleable tube 18 are made is also used in this calculation. For a more detailed discussion of this concept see, "Concept and Applications of Finite Element Analysis", Second Edition, Robert D Cook, Department of Engineering Mechanics, University of Wisconsin-Madison, John Wiley & Sons, 1981. The shorter the length of the wire strands 14, and thus the smaller the circumference of the prosthesis, the greater the stiffness. For example, a ring prosthesis of 26 millimeters would have a ring spring rate of 160 grams per millimeter, while a ring prosthesis of 38 millimeters would have a ring spring rate of 240 grams per millimeter.

The ring prosthesis 10 further includes an outer sheath 20. this outer sheath 20 fits snugly wrapped about the wire strands 14. This sheath 20 may be any suitable type of biocompatible material, for example a knit fabric such as Dacron polymer (polyethylene terephthalate) fabric.

The wire strands may be embedded in an elastomeric material, or coated with an elastomeric material or polytetrafluoroethylene to reduce friction between the individual wire strands 14, and thus minimize wear.

The substantially straight side 12 of the ring prosthesis bows outward from a plane in which lies the remainder of the ring prosthesis 10. This is seen better in Figure 3. Generally, the outward curvature of the straight side 12 provides an angle between a line drawn along the side 12, seen generally at 13, and that plane in which lies the remainder of the ring prosthesis 10, seen at 15, of from about 0° to about 15°. This curvature is preferably designed to conform to the geometry of that portion of the mitral valve annulus adjacent to the aortic valve root, and provides for a more compatible fit of the annuloplasty ring prosthesis 10 about the mitral valve.

In another construction the side 12 is not substantially straight, but is formed with a slight outward curvature as seen in phantom at side 16'.

While the ring prosthesis described and illustrated in Figures 1 through 3 provides an improvement over presently available ring prostheses, other more preferable constructions will now be described. These provide for a greater degree of control in the flexing of the prosthesis during the normal opening and closing of the associated heart valve and also ensure that the load applied to the prosthesis is evenly applied to the prosthesis structure. The individual wire strands 14 of the prosthesis illustrated in Figures 1-3, are free to move with respect to each other. This movement allows the wire strands 14 to rub against each other which causes unwanted wear. Also, the load applied to the ring prosthesis 10, as the valve opens and closes, unevenly varies between the individual strands 14. This may result in the concentration of the applied load onto one or more of the wire strands 14, which may also result in stress fatigue of those strands 14.

One prosthesis according to the invention is illustrated in Figures 4 and 6 at 22. In this embodiment the selectively flexible body element comprises a multi-lumen elastomeric tube 28, with individual wire strands 24 fitted in respective ones of the individual lumens 26. The positioning of the wire strands 24 in the associated lumens 26 restricts the movement of the strands 24 with respect to each other. This ensures that the load will be borne evenly by the individual strands 24. Furthermore, the individual wire strands 24 can not rub against each other. This reduces the wearing of the strands 24.

The number of individual wire strands 24 used to construct this embodiment is dependent upon flexibility desired for the prosthesis 22. Generally,

from about 2 to about 9 individual strands 24 are used to construct the prosthesis 22, with the individual strands 24 having similar dimensions and prepared from a similar material to that used for the wire strands 14 of the previously described prosthesis.

The prosthesis 22 is also designed to have selective flexibility. This selective flexibility is provided by forming about the circumference of the prosthesis 22 one or more defined lengths, one of which is seen generally at 30, which are substantially more rigid than the remainder of the prosthesis 22 circumference. The prosthesis 22 is designed so that the flexibility of the prosthesis increases in a direction away from these lengths 30. The rigid lengths 30 of the prosthesis 22 may be formed by any suitable method, such as those methods described above for the rigid length 16 of the previously described prosthesis.

In the illustrated embodiment, the multi-lumen elastomeric tubing 28, as seen in Figure 4, does not run the entire circumference of the ring prosthesis 22. A portion of this elastomeric tubing 28 is removed, or the length of such tubing 28 is provided to expose a portion of the wire strands 24, preferably at a location adjacent to the position at which the wire strands 24 abut. The abutting ends of the wire strands 24 are held together by any suitable manner. A malleable tube 32 is secured about the wire strands 24 at this exposed location in a manner as described above. The crimping, pinching or welding of the tube 32 defines the rigid length 30. As with the previously described prosthesis, the size of this rigid length 30 is determined by the extent to which the tube 32, and adjacent portions of the wire strands 24 are crimped, pinched or welded. The arrangement of the individual wire strands 24 in the associated lumens 26 is seen better in Figure 6, while the placement of the wire strands 24 in the malleable tube 32 is best seen in Figure 7.

The illustrated ring prosthesis 22 is also designed with a substantially straight side, seen generally at 34. This straight side 34 is similar to the straight side 12 as described above for the previously described prosthesis, and will not be described in any greater detail herein. Furthermore, this straight side 34 may be curved outward in a manner similar to side 16' in Fig.1, with this side 34 also preferably being formed outwardly curving as seen at 34'.

Referring now to Figures 8 through 11 ring prosthesis of the invention, seen generally at 36, will be described. In this embodiment the selectively flexible body element of the annuloplasty ring prosthesis 36 is defined by a spiral wire band structure. The individual spiral layers are formed by selectively wrapping a single band to form the spiral structure, or by layering individual bands 38 upon one another. Preferably a plurality of individual bands 38 are layered upon one another to form the multi-layered structure. The ring prosthesis 36 may include from one to about 6 of these spiral layers. These bands 38 are formed from a biocompatible, anti-magnetic material.

This spiral structure is held within a cloth sheath 40 in a manner similar to the previously described embodiments. Preferably, in order to reduce friction between adjacently positioned bands, an elastomeric material is placed between the individual spiral layers, e.g. the individual bands 38, with such material seen at 37 in Figure 10. The elastomeric material 37 also surrounds the outside of the bands 38. As seen in Figures 10 and 11, the cloth sheath 40 bulges outwards along one side, with this bulge, as seen at 41, filled with the elastomeric material 37. This bulge 41 is preferentially positioned along the outside of the prosthesis 36. Sutures will be passed through the bulge 41.

The selectively flexible body element, as defined by the spiral band 38 structure is also formed about its circumference with one or more defined lengths, one of which is seen generally at 42, which are substantially more rigid than the remainder of the body element circumference. This aspect of prosthesis 36 is similar to the previously discussed embodiments, and will not be described in great detail herein. The rigid length 42 is typically formed by crimping or spot welding the individual bands 38 together for the desired length.

As seen in Figure 11, none of the elastomeric material 37 is positioned between the bands 38 along the rigid length 42. This occurs because the individual bands 38 are overlapped at this location. That is the respective ends, not shown, of each band 38 are overlapped. Preferably the respective ends are tapered. This better distributes the stresses exerted upon the prosthesis 36 than if the respective ends were merely squared off.

The desired size of this rigid length 42 is also similar to that of the above described embodiments. Generally, this rigid length 42 is from about 1/8 to about 1/2 of the ring prosthesis 36 circumference. The flexibility of the body element also varies in a direction away from this rigid length 42 in a manner similar to that described for the previous embodiments. That is, preferably a ratio of the stiffness of the body element, as defined by the spiralled bands 38 in the longitudinal direction over the stiffness in the lateral direction is from about 1.15 to about 2.77.

The use of a spiralled structure prepared by the overlaying of one or more bands 38 ensures that the force applied against the prosthesis 36 is better distributed over the various layers of the bands 38. That is, the application of force against

the prosthesis 36 is better distributed to the various band 38, than is distributed to the individual wire strands 24, in the embodiment of Figures 4-7, or strands 14, in the embodiment of Figures 1-3. The result is a more even application of load to the entire ring prosthesis 36 in both the longitudinal and lateral directions.

The precise number of spiral windings forming the body element is dependent upon the materials used for the bands 38, as well as the thickness of the individual band 38 layers forming the multi-layered structure. Generally, from about 1 to about 6 spiral layers or individual bands 38 are used, while the thickness of each layer or band 38 may be from about 0.05mm (0.002 inch) to about 0.2mm (0.008 inch).

## Claims

1. An annuloplasty ring prosthesis for suturing about a heart valve annulus comprising a selectively flexible body member having a substantially annular shape proportional to fit about the circumference of said heart valve annulus, said body member being formed at one or more positions about its circumference with one or more defined lengths (16,30,42) which are substantially more rigid than the remainder of said body member circumference, said member gradually increasing in flexibility about its circumference in a direction away from the, or each of said defined rigid lengths; and means (20) for encapsulating said body member and formed to permit suturing of said ring prosthesis about said heart valve,

   characterised in that the body member is formed from a plurality of wire elements (14,24,38), the elements being wire strands (14,24) or wire band layers (38),

   the wire strands (14) being formed into a bundle with said defined lengths (16,30) being formed by fixing the wire strands together, or

   the wire strands (24) being positioned individually in lumens (26) of a multiple lumen tubular enclosure (28), or

   the wire band layers (38) being formed from one or more individual substantially flat bands wrapped upon one another to form a multiple layered structure.

2. The annuloplasty ring prosthesis of Claim 1 wherein the wire strands (14) of said bundle are individually coated with polytetrafluoroethylene or an elastomeric material.

3. The annuloplasty ring prosthesis of Claim 1, wherein said bundle of individual strands is embedded in an elastomeric material.

4. The annuloplasty ring prosthesis of any preceding claim wherein each said defined rigid length (16,30) is formed by positioning a malleable material (18) around a portion of said wire strands (14,24) which is to define said rigid length, and pinching said material down upon said strands.

5. The annuloplasty ring prosthesis of Claim 4, wherein said malleable material is pinched down upon said strands (24) after a portion of said multiplo-lumen tube (28) is removed to expose said wire strands.

6. The annuloplasty ring prosthesis of Claim 1 wherein said body member is formed from a single wound band (38).

7. The annuloplasty ring prosthesis of Claim 1 wherein said body member is formed from a plurality of individual bands (38).

8. The annuloplasty ring prosthesis of Claim 6 or 7 wherein said defined rigid length is formed by crimping or welding together a length of said individual band (38), or a length of said individual bands (38).

9. The annuloplasty ring prosthesis of any preceding claim wherein said body member includes only one of said defined rigid lengths (16,30,42) which rigid length is defined by from about 1/8 to about 1/2 of the circumference of said body member.

10. The annuloplasty ring prosthesis of any preceding claim wherein said body member is configured with two opposing longitudinal sides being longer than intervening lateral sides, said rigid length or lengths (16,30,42) being defined along one of said longitudinal sides (12).

11. The annuloplasty ring prosthesis of Claim 10 wherein one of said longitudinal sides (12) is substantially straight, and wherein said rigid length (16,30,42) is defined along at least part of said substantially straight longitudinal side.

12. The annuloplasty ring prosthesis of Claim 10 wherein said substantially straight longitudinal side (12) is defined along from about 1/5 to about 1/3 of the circumference of said member.

13. The annuloplasty ring prosthesis of Claim 11 wherein said rigid length (16,30,42) is defined along from about 5/8 to about the entire length of said straight side (12).

14. The annuloplasty ring prosthesis of Claim 10, 11, 12 or 13 wherein a ratio of a stiffness, as measured by the spring rate in a longitudinal direction over the spring rate in a lateral direction is from about 1.15 to about 2.77.

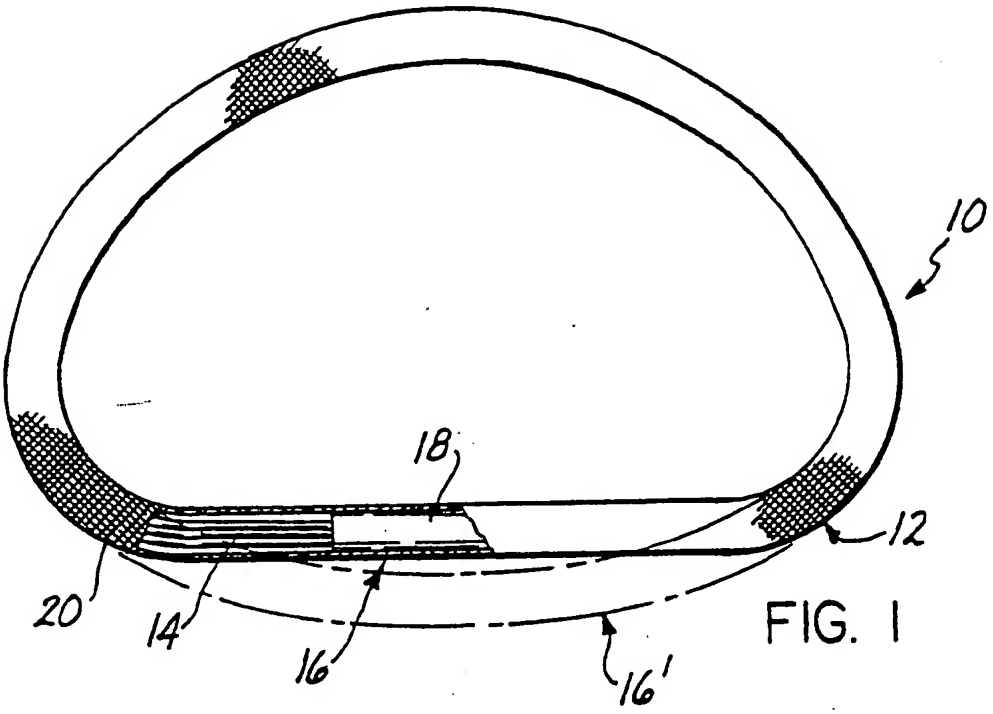



FIG. 1

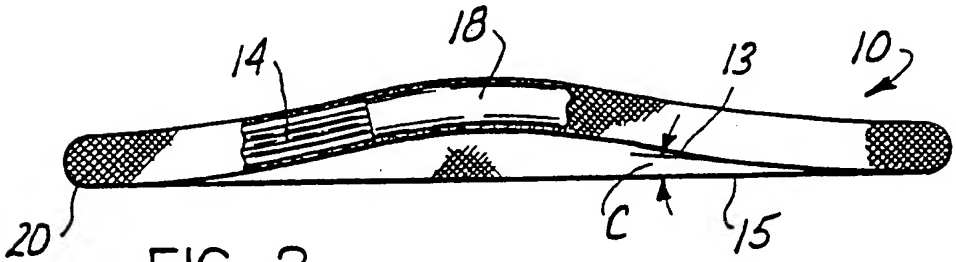



FIG. 2

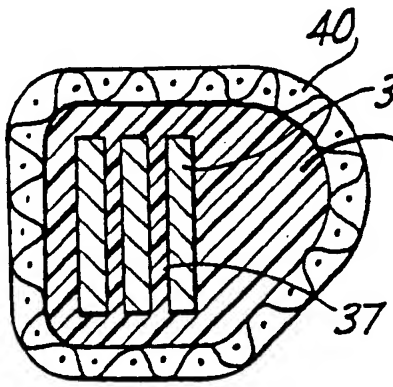



FIG. 10

FIG. 4

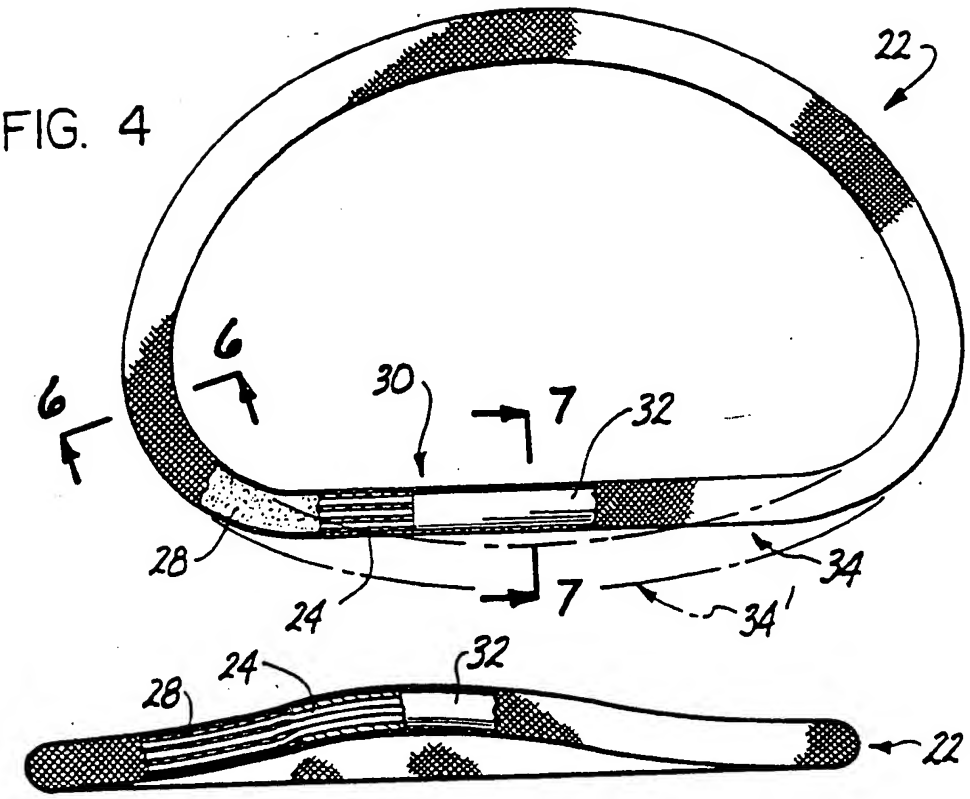






FIG. 5

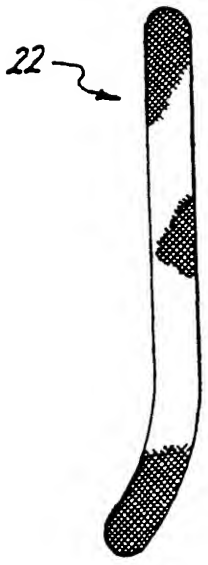
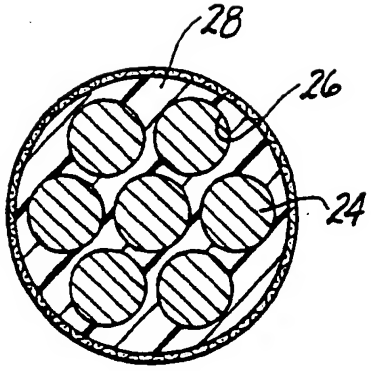



FIG. 3

FIG. 6



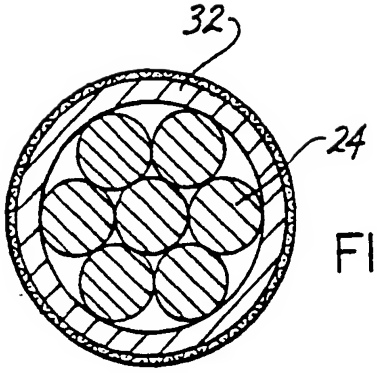




FIG. 7

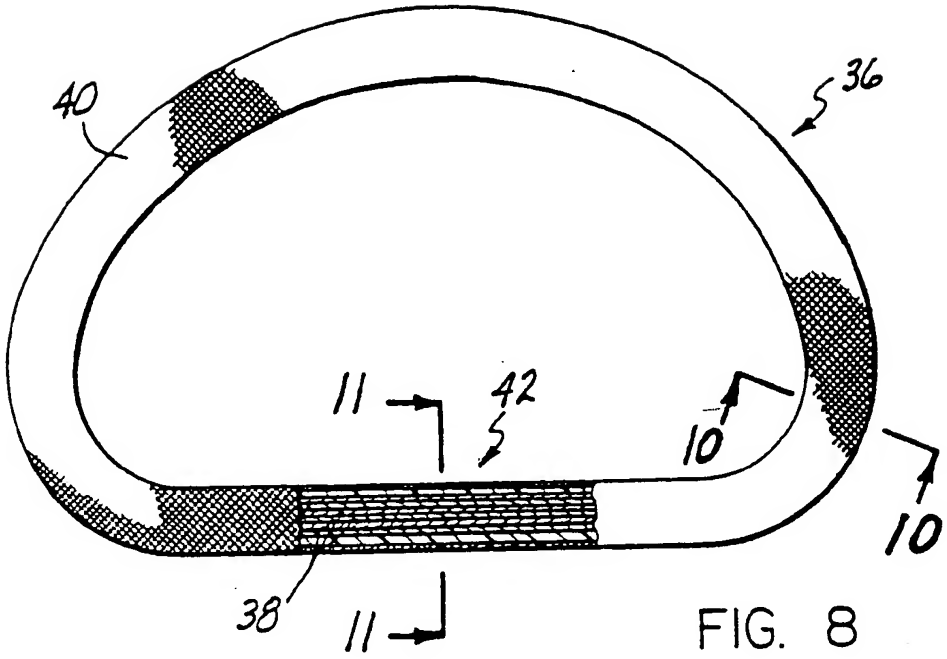



FIG. 8

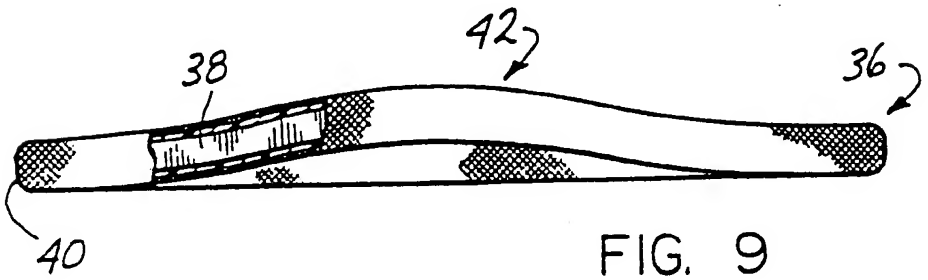



FIG. 9

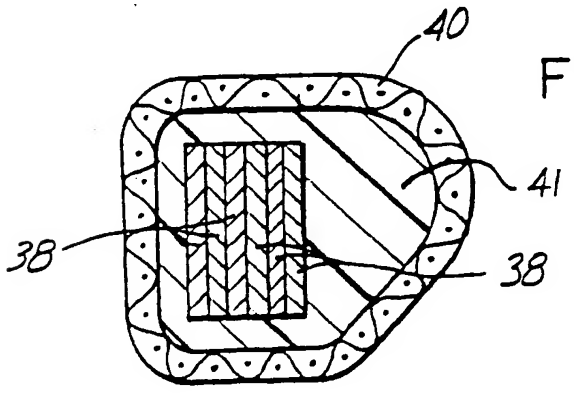



FIG. 11

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## (54) Annuloplasty ring prosthesis.

(57) An annuloplasty ring prosthesis has a flexible, annular body including one or more defined lengths (16,30), which are more rigid than the remainder of the body. The flexible body increases in flexibility about its circumference in a direction away from the, or each rigid, defined length and is formed from a plurality of individual wire elements. The elements may be wire strands (14,24) secured in a bundle, positioned in respective lumens (26) of a multiple lumen enclosure (28), or may be layers (38) of one or more wire bands wrapped on one another.

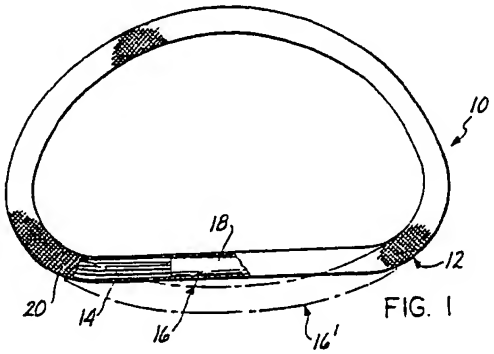


FIG. 1

EP 0 595 791 A3

European Patent Office

# EUROPEAN SEARCH REPORT

Application Number
EP 94 20 0002

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int.Cl.5) |
|---|---|---|---|
| A | EP-A-0 257 874 (BAXTER TRAVENOL LABORATORIES, INC.) | 1,6,8-14 | A61F2/24 |

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61F

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| STOCKHOLM | 12 April 1994 | BRANDER LEIF |

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